

# **EXHIBIT M**

Declaration of Stephanie McGee Azar, Commissioner of the Alabama Medicaid Agency

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF TENNESSEE  
KNOXVILLE DIVISION**

STATES OF TENNESSEE, ALBAMA, )  
ARKANSAS, GEORGIA, IDAHO, INDIANA, )  
IOWA, LOUISIANA, MONTANA, )  
NEBRASKA, NORTH DAKOTA, OHIO, )  
SOUTH CAROLINA, SOUTH DAKOTA, and )  
WEST VIRGINIA, )

*Plaintiffs,* )

v. )

U.S. DEPARTMENT OF HEALTH AND )  
HUMAN SERVICES; XAVIER BECERRA, in )  
his official capacity as Secretary of Health and )  
Human Services; and U.S. DEPARTMENT OF )  
HEALTH AND HUMAN SERVICES OFFICE )  
OF CIVIL RIGHTS, )

*Defendants.* )

Civil Action No. 25-cv-25

**DECLARATION OF STEPHANIE MCGEE AZAR**

Pursuant to 28 U.S.C. § 1746, I, Stephanie McGee Azar, duly affirm under penalty of perjury as follows:

1. I am over 18 years of age, have personal knowledge of the matters set forth herein, and am competent to make this declaration.

2. I serve as the Commissioner of the Alabama Medicaid Agency. The Alabama Medicaid Agency is the single state agency charged with administering the Medicaid program in Alabama in accordance with Title XIX of the Social Security Act. Ala. Code §22-6-7(a). Two of the many responsibilities I oversee in administering the program are verifying whether services reimbursed were actually furnished to beneficiaries and responding to judicial demands. See 42 C.F.R. 455.1(a); 45 C.F.R. § 164.512.

3. The Program Integrity Division of the Alabama Medicaid Agency conducts investigations using methods that do not infringe on the legal rights of the persons involved. 42 C.F.R. §455.13(b)(1). One such method is requesting records from the provider to substantiate the medical necessity of services. The provider has a legal duty to maintain such records and furnish them to Medicaid. 42 C.F.R. §431.107(b)(1)-(2). These records may contain information possibly related to reproductive health care.

4. The Office of General Counsel of the Alabama Medicaid Agency responds to subpoenas issued by Courts of competent jurisdiction. Fed. R. Civ. P. 45(e)(1); Ala. R. Civ. P. 45(d). Medicaid redacts the information in subpoenas in accordance with federal and state law. *See* 42 C.F.R. §2.13(a); *See also* Ala. Code §22-11A-22. The subpoenas are often for claims data that is rife with information possibly related to reproductive health care.

5. I have reviewed the Department of Health and Human Services' *HIPAA Privacy Rule to Support Reproductive Health Care Privacy*, 89 Fed. Reg. 32,976 (Apr. 26, 2024) (the "Final Rule"), which took effect on June 25, 2024, although compliance with the Final Rule generally was not required until December 23, 2024, *id.* at 32,976.

6. The Final Rule has created barriers to investigations and costs in complying with subpoenas.

7. Promulgated in response to the Supreme Court's decision in *Dobbs v. Jackson Women's Health Organization*, 597 U.S. 215 (2022), the Final Rule places limits on the disclosure and use of patient information related to "reproductive health care," which it broadly defines as "health care ... that affects the health of an individual in all matters relating to the reproductive system and to its functions and processes," 45 C.F.R. § 160.103.

8. Specifically, the Final Rule prohibits covered entities from disclosing PHI where it will be used for any of the following activities:

- (1) To conduct a criminal, civil, or administrative investigation into any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care.
- (2) To impose criminal, civil, or administrative liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care.

45 C.F.R. § 164.502(a)(5)(iii)(A).

9. If the covered entity concludes that one of these two conditions exists, it cannot disclose the requested information if it “reasonably determine[s]” that the “reproductive health care,” at issue is either (1) “lawful under the law of the state in which such health care is provided under the circumstances in which it is provided,” or (2) “protected, required, or authorized by Federal law, including the United States Constitution, under the circumstances in which such health care is provided, regardless of the state in which it is provided.” *Id.* § 164.502(a)(5)(iii)(B).

10. In making that assessment, the Final Rule creates a presumption that reproductive health care provided by another person is lawful under (a)(5)(iii)(B)(1) or (2)—and so not subject to investigation by a State—unless the covered entity or business associate has either:

- (1) Actual knowledge that the reproductive health care was not lawful under the circumstances in which it was provided[, or];
- (2) Factual information supplied by the person requesting the use or disclosure of protected health information that demonstrates a substantial factual basis that the reproductive health care was not lawful under the specific circumstances in which it was provided.

*Id.* § 164.502(a)(5)(iii)(C).

11. The covered entity that receives a request for PHI itself makes these determinations—including legal assessments of state and federal laws. And if the covered entity

determines that any of the conditions barring disclosure exist, it may deny the request. The Final Rule does not provide explicit recourse for the requesting entity.

12. Under the Final Rule, covered entities also must require attestations with a request for PHI that is potentially related to “reproductive health care” data. *Id.* § 164.509(a). Such attestations are required under the Final Rule even when regulatory conditions on disclosures for law enforcement purposes are otherwise met. *See id.*; *id.* § 164.512(f)(1)-(6)

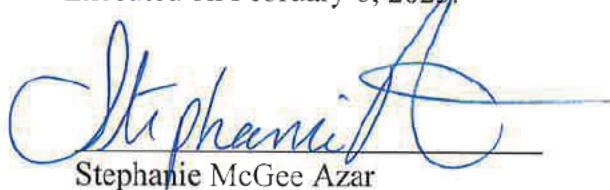
13. The Alabama Medicaid Agency has had to expend significant time and resources to determine how to comply with the Final Rule’s requirements because they are vague and overbroad.

14. Through this vagueness, entities that are under investigation by the Program Integrity Division can slow the investigation by refusing to provide reproductive health care information even though it is not requested for a forbidden purpose. The only recourse the Alabama Medicaid Agency has to such a demand is to either seek an injunction in court or disenroll the provider for non-compliance with the provider agreement. *See* 42 C.F.R. §431.107(b)(1)-(2).

15. The overbroad requirements of the Final Rule now requires staff to expend much more time redacting information from lawful demands. Information potentially related to reproductive health care includes not only diagnosis such as contraception and birth, but also diagnosis such as dermatitis, cancer, or vomiting if the diagnosis is due to anything *possibly related* to reproductive organs or functions. The number of redactions required, and the time implementing those redactions, has ballooned. The sheer quantity of redactions has forced the Alabama Medicaid Agency to explore technological solutions so the limited staff can return their focus to streamlining the provision of healthcare payments for eligible Alabamians.

16. Ultimately, the Final Rule complicates the Alabama Medicaid Agency's response to judicial demands. Because of the Final Rule, responding to subpoenas will consume more resources than before the Final Rule's effective date. Because of that, the Final Rule is impacting the public health of the State of Alabama because it has added new expenses and staff resources that would otherwise be focused on health care.

Executed on February 6, 2025.

A handwritten signature in blue ink, appearing to read "Stephanie McGee Azar". The signature is fluid and cursive, with a stylized 'S' and 'A'. It is positioned above a solid blue horizontal line.

Stephanie McGee Azar